

# FOOD AND DRUG ADMINISTRATION

Center for Drug Evaluation and Research

*Oncologic Drugs Advisory Committee*

## AGENDA

September 1, 2009

8:00 a.m.	Call to Order Introduction of Committee	<b>S. Gail Eckhardt, M.D.</b> Chair, ODAC
	Conflict of Interest Statement	<b>Nicole Vesely, Pharm.D.</b> Designated Federal Official, ODAC

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*The committee will discuss supplemental NDA (sNDA) 021-673/S-009, CLOLAR (clofarabine) Injection for intravenous use, Genzyme Corporation, proposed indication for the treatment of previously untreated adults aged 60 years or older with acute myeloid leukemia with at least one unfavorable baseline prognostic factor.*

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8:15 a.m.	<b><u>Guest Speaker</u></b>	
8:40 a.m.	<b><u>Sponsor Presentation</u></b>	<b><u>Genzyme Corporation</u></b>
9:20 a.m.	<b><u>FDA Presentation</u></b>	<b><u>sNDA 021-673/S-009</u></b>
10:00 a.m.	<i>Break</i>	
10:15 a.m.	Questions to the Presenters	
10:45 a.m.	Open Public Hearing	
11:15 a.m.	Questions to the ODAC and ODAC Discussion	
12:15 p.m.	<i>Lunch</i>	

# FOOD AND DRUG ADMINISTRATION

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## AGENDA

September 1, 2009

1:15 p.m.	Call to Order Introduction of Committee	<b>S. Gail Eckhardt, M.D.</b> Chair, ODAC
	Conflict of Interest Statement	<b>Nicole Vesely, Pharm.D.</b> Designated Federal Official, ODAC

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*The committee will discuss New Drug Application (NDA) 022-489, proposed trade name ONRIGIN (laromustine) Injection, Vion Pharmaceuticals, Inc., proposed indication for remission induction therapy for patients 60 years or older with de novo poor-risk acute myeloid leukemia (AML).*

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1:25 p.m.	<b><u>Sponsor Presentation</u></b>	<b><u>Vion Pharmaceuticals, Inc.</u></b>
2:05 p.m.	<b><u>FDA Presentation</u></b>	<b><u>NDA 022-489</u></b>
2:45 p.m.	<i>Break</i>	
3:00 p.m.	Questions to the Presenters	
3:30 p.m.	Open Public Hearing	
4:00 p.m.	Questions to the ODAC and ODAC Discussion	
5:00 p.m.	Adjourn	